



Bundesnetzagentur

How to perform a risk assessment in accordance with Directive 2014/53/EU?

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REDCA, Copenhagen, 15-May-2018



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Overview

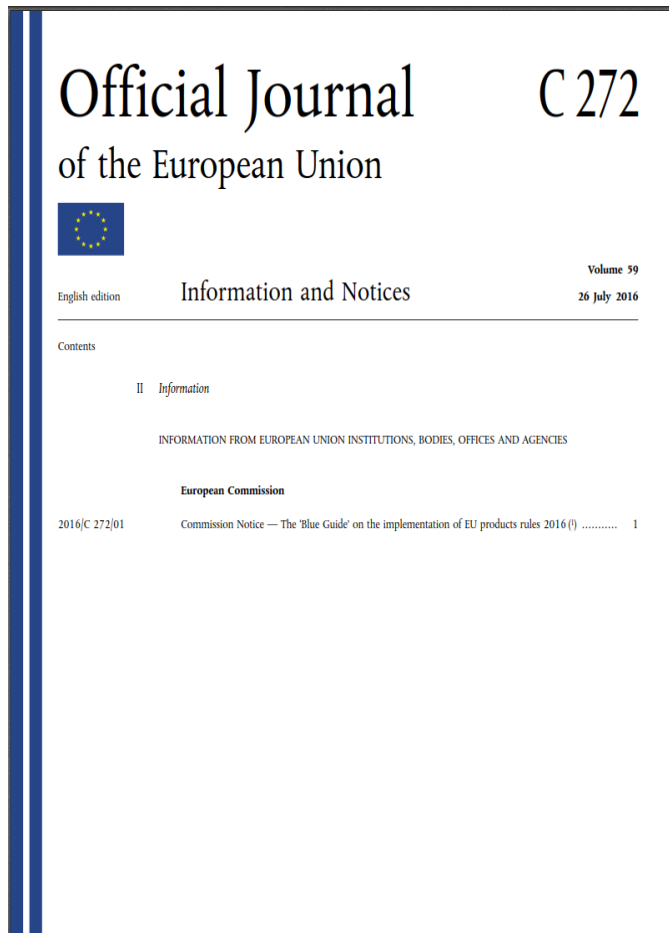
- Directive 2014/53/EU
- Blue Guide
- Methods of risk assessment
- Steps for a risk assessment
- Examples of additional risk assessments
- Tools
- Recommended minimum requirements for a risk assessment

Directive 2014/53/EU

- The manufacturer submits technical documentation for the EU type examination (Annex III RED module B No. 3 c).
- The technical documentation must include an adequate analysis and assessment of the risk(s).
- Risk assessment is required without exception, even if harmonised standard(s) applied (a harmonised standard cannot cover every risk for every product, example intermodulation of multiple transmitters).
- The manufacturer needs to document the assessment of how they are addressing the identified risks (reasonable /foreseeable” use).

Which method(s) for risk analysis and assessment is/are appropriate for the manufacturer?

Blue Guide 1/5



- The Blue Guide is intended to contribute to a better understanding of EU product rules and to their more uniform and coherent application across different sectors and throughout the single market.
- This is intended purely as a guidance document – only the text of the Union harmonization act itself has legal force.
- The Blue Guide is a horizontal document including guidelines for all CE-marking directives.
- You can also find additional, more specific guides, e.g. the current RED Guide.
- These guides typically do not refer to horizontal questions. Risk Assessment is a horizontal issue. So the requirements are described in the Blue Guide.

Blue Guide 2/5

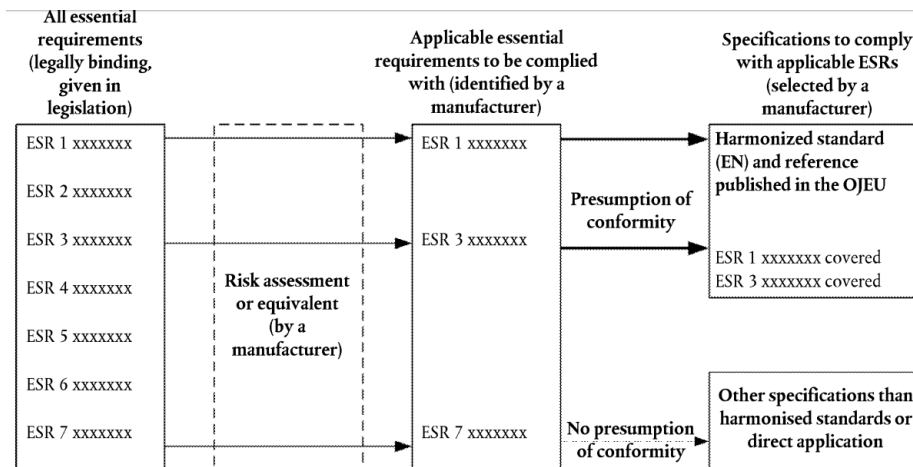
- ... Therefore, manufacturers have to carry out a risk analysis to first identify all possible risks that the product may pose and determine the essential requirements applicable to the product (151).
(151) For the technical documentation...
- In addition, the manufacturer needs to document the assessment of how he is addressing the risks identified to ensure that the product complies with the applicable essential requirements (for example, by applying harmonised standards). If only part of the harmonised standard is applied or it does not cover all applicable essential requirements, then the way applicable essential requirements not covered by it are dealt with, should be documented (152).
(152) Even where the manufacturer uses a harmonised standard (where its reference is published in the OJ and which aims to cover certain risks) to satisfy essential requirements, the risk assessment has to be carried out and he must check whether the harmonised standard covers all risks of the product. This is because it cannot be assumed that the harmonised standard covers all requirements of all legislative acts applicable to a given product (or, indeed, all the requirements of the specific act under which it has been developed) or whether the product in question introduces also other risks not considered in the harmonised standard.

Blue Guide 3/5

- The European harmonized legislation on CE-marking is risk related.
- Manufacturers have to carry out and document their risk analysis and assessment.
- Manufacturers first need to identify all possible risks of the product considering the intended purpose and taking account of 'reasonably foreseeable misuse'.
- In risk related harmonization legislation a manufacturer always remains fully responsible for assessing all the risks of his product in order to determine which essential requirements are applicable.
- After this risk analysis a manufacturer may then choose to apply specifications given in harmonized standards to implement 'risk reduction measures' which are specified by the harmonized standards.

Blue Guide 4/5

- Harmonized standards provide a presumption of conformity with the essential requirements they aim to cover, if their references have been published in the Official Journal of the European Union.
- References of harmonized standards are published as Commission Communications in the C series of the Official Journal of the EU.



Blue Guide 5/5

- The manufacturer needs to document the assessment of how he is addressing the risks identified.
- Even when using harmonized standards, the risk assessment has to be carried out.
- The manufacturer must check whether the harmonized standard covers all risks arising from the product, because:
 - The harmonized standard may not cover all requirements of all legislative acts applicable to the product.
 - Or the product introduces also other risks not considered in the harmonized standard.

Steps for a risk assessment

- Assessment of risks from the characteristics of the device and from the intended and foreseeable use/misuse of the device
- Search for harmonised standard or other specifications to minimize the risks
- Search for open risks which are not described in harmonized standards, use standards or other ways to mitigate risks
- Additional testing/assessment of open risks, if required
- Documentation in risk assessment as part of the Technical Documentation (TD)

Tools may be used for Risk Assessment RED Article 3.1a) on Safety and Health

- CENELEC Guide 32: Guidelines for Safety Related Risk Assessment and Risk Reduction for Low Voltage Equipment.
- This guide has a very good structured checklist in Annex D, Table D.1, Risk assessment documentation.
- The list in Appendix D of CENELEC Guide 32 could also provide a structural basis for aspects such as beyond electrical safety (but not all points are detailed enough, see A.6.3/A.6.4).

Example:

Requirement	Relevant Yes / No	Fulfilled by
A.4 Protection against electrical hazards		
a) Leakage current	Yes	Application of EN 60950-1, see Test Report ...
b) Energy supply	Yes	Application of ..., see Test Report ... and User Information

Tools may be used for Risk Assessment RED Article 3.1b) on EMC

- EN 61000-4-1: This standard gives a good overview on electromagnetic phenomena in immunity testing.
- ETSI EG 203 336: This standard could be helpful in the selection of relevant phenomena in the field of radio.
- The object is to give assistance to manufacturers in:
 - considering the immunity test methods applicable to their products,
 - determining the immunity test methods relevant for the electromagnetic environment in which their products are intended to be used,
 - specifying the parts of their products being subjected to the relevant immunity test methods.

Recommended minimum information in a risk assessment:

- Intended use and environment conditions
- Applicable EU-Directives including essential requirements (ESR)
- Applicable ESR to the specific device
- List of used harmonised standards in relation to the ESR
- List of additional standards/ tests, if applicable

We would recommend to develop a TGN which includes minimum requirements on a risk assessment.



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REDCA, COPENHAGEN, 15-May-2018